

Radio-Frequency Energy Delivery to the Anal Canal for the Treatment of Fecal Incontinence

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PURPOSE: In this prospective study we investigated the feasibility, safety, and efficacy of radio-frequency energy delivery deep to the mucosa of the anal canal for the treatment of fecal incontinence. **METHODS:** We studied ten patients with fecal incontinence of varying causes. All patients underwent anoscopy, anorectal manometry, endorectal ultrasound, and pudendal nerve terminal motor latency testing at baseline and six months. The Cleveland Clinic Florida scale for fecal incontinence (Wexner, 0–20), fecal incontinence-related quality of life score, and Short Form 36 were administered at baseline, 1, 2, 3, 6, and 12 months. Using conscious sedation and local anesthesia, we delivered temperature-controlled radio-frequency energy *via* an anoscopic device with multiple needle electrodes to create thermal lesions deep to the mucosa of the anal canal. **RESULTS:** Ten females (age, 55.9 ± 9.2 years; range, 44–74) were enrolled and treated. Median discomfort by visual analog scale (0–10) was 3.8 during and 0.9 two hours after the procedure. Bleeding occurred in four patients (14–21 days after procedure), spontaneous resolution ($n = 3$) and anoscopic suture ligation ($n = 1$). At 12 months, the median Wexner score improved from 13.5 to 5 ($P < 0.001$), with 80 percent of patients considered responders. All parameters in the fecal incontinence-related quality of life were improved (lifestyle (from 2.3 to 3.4), coping (from 1.4 to 2.7), depression (from 2.2 to 3.5), and embarrassment (from 1.3 to 2.8); $P < 0.05$ for all parameters). Protective pad use was eliminated in five of the seven baseline users. At six months, there was a significant reduction in both initial and maximum tolerable rectal distention volumes. Anoscopy was normal at six months. **CONCLUSION:** Radio-frequency energy delivery to the anal canal for treatment of fecal incontinence is a new modality that, in this study group, safely improved Wexner and fecal incontinence-related quality of

life scores, eliminated protective pad use in most patients, and improved patient quality of life. [Key words: Fecal incontinence; Radio frequency; Anal canal; Anorectal manometry; Sphincter; Injury]

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Fecal incontinence (FI) affects between 2 and 8 percent of U.S. adults.^{1,2} Causes include the presence of sphincter defects caused by trauma, surgery, or vaginal childbirth, congenital abnormalities, chronic diarrhea or constipation, pudendal neuropathy, and specific systemic medical diseases.³ The stigmata associated with FI are severe, often resulting in a dramatic reduction in patient quality of life (QOL).⁴

Fecal incontinence management often begins with nonsurgical interventions, including diet modification, antimotility agents, Kegel exercises, biofeedback, or controlled evacuation. Surgical management may be an option for patients with insufficient response to, or inability to cooperate with, conservative modalities. Surgery is tailored according to the specific cause of FI and patient anatomy, and most commonly involves overlapping sphincter repair.⁵ Other techniques have been used, but are used less often, including the Thiersch procedure,⁶ stimulated gracilis muscle flap,⁷ posterior sphincter repair,³ and reefing procedures.³ New technologies being evaluated include artificial bowel sphincter implantation⁸ and sacral nerve stimulation.⁹

A minimally invasive, endoanal outpatient procedure that reduces the involuntary passage of liquid and solid stool would be of potential benefit to pa-

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tients, particularly if performed under local anesthesia. Based on the therapeutic effect of temperature-controlled radio-frequency (RF) energy delivery to the lower esophageal sphincter for the treatment of gastroesophageal reflux disease,¹⁰ we hypothesized that delivery of RF energy to the anal canal could potentially improve the barrier function of the anal sphincter complex. This premise is based on the tissue tightening effects that occur with RF heating: collagen contraction, focal wound healing, remodeling, and tissue compliance reduction.¹¹ RF energy has been used effectively for tightening tissue in obstructive sleep apnea,¹² snoring,¹³ benign prostatic hyperplasia,¹⁴ and joint capsule laxity.¹⁵ The purpose of this study was to evaluate the safety, tolerability, and effectiveness of RF energy delivery deep to the mucosa of the anal canal for the treatment of FI.

PATIENTS AND METHODS

Before commencing this human study, an animal study was conducted at the Stanford/VA Palo Alto Health Care System Animal Research Facility to evaluate the safety of RF energy delivery to the anal canal with respect to pudendal nerve terminal motor latency (PNTML), anorectal manometry (ARM), and endorectal ultrasound (ERUS) at baseline, acutely after treatment, and at six weeks. The anal mucosa was intact at six weeks and there was no change in PNTML or ARM. There were small focal areas of fibrosis within the anal sphincter and thickening of the anoderm on ERUS. There were no infections, strictures or bleeding.

Study Population

Patients were recruited from the pool of patients of the Department of GI Motility Disorders at the Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico City, Mexico that were dissatisfied with the results of medical and biofeedback therapy for FI. All patients enrolled had experienced FI for at least three months, had FI at least once per week, and had attempted, but were unsatisfied with, lifestyle and diet modification, bulking agents, pharmacologic therapy, and biofeedback. Subjects were necessarily American Society of Anesthesiologists physical status I to III, age ≥ 18 and < 80 years, and able to participate in and understand the study and sign the consent form. Patients were excluded if they met any of the following criteria: prior surgery for FI

(excluding primary episiotomy repair), inflammatory bowel disease, collagen vascular disease, active anal fissure, fistula or abscess, constipation or chronic diarrhea as sole cause or the major contributor to FI, abnormal blood coagulation or active use of anticoagulant or platelet antiaggregation therapy, prior pelvic irradiation, pregnancy, history of laxative abuse, or unstable psychiatric disorder(s).

Study Design

This was a single-center, prospective study involving ten patients with FI, conducted under an approved institutional review board protocol at the Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico City, Mexico. Subjects who met the criteria for the study underwent the informed consent process and signed the consent form. All enrolled subjects had a complete history, a physical examination, and anoscopy. A serum pregnancy test for females of childbearing age (obtained 7 days before the procedure) was performed.

Stationary pull-through anorectal manometry was performed at baseline and six months using a water-perfused system and computer software (Medtronic, Minneapolis, MN). Endorectal ultrasound was performed at baseline and six months using a standard 7 MHz probe (B-K Medical, Copenhagen, Denmark). Pudendal nerve terminal motor latency analysis was performed at baseline and six months using a glove-mounted electrode connected to a pulsed stimulus generator (St. Mark's Electrode™, Dantec generator, Medtronic Functional Diagnostics, Minneapolis, MN).

All subjects completed the fecal incontinence grading scale (Wexner),³ the fecal incontinence quality of life questionnaire (FIQL),⁴ and the Medical Outcomes Study Short Form 36 (SF-36).¹⁶ Patients discontinued use of platelet-inhibiting medications seven days before treatment and were not permitted to restart until three weeks after treatment. Patients administered enemas one hour before their procedures.

Radio-Frequency Energy Delivery Technique

Subjects were treated in the ambulatory surgery unit using local anesthesia and monitored anesthesia care. One investigator (TT) performed all procedures. The patients were positioned prone in the jackknife position. A standard electrosurgical dispersive electrode pad was placed on the patient's buttock accord-

ing to the hospital safety standards. A specially designed four-channel RF energy generator was used (Curon Medical, Sunnyvale, CA). A bag of sterile plain water was spiked with intravenous tubing, and the tubing was installed in the integrated peristaltic pump on the generator.

Fentanyl and midazolam were administered for sedation. Antibiotic prophylaxis consisted of intravenous cefuroxime (1.5 gm) and metronidazole (500 mg). A perianal and pudendal nerve block was performed with 30 ml of a 1:1 mixture of 1 percent lidocaine with 1:100,000 epinephrine and 0.25 percent bupivacaine with 1:100,000 epinephrine. Digital examination and anoscopy were performed.

The RF energy hand piece is comprised of an anoscopic barrel with four nickel-titanium curved needle electrodes (22 gauge, 6 mm in length; Curon Medical, Sunnyvale, CA). Thermocouples are present within the tip and at the base of each needle to monitor tissue and mucosal temperatures, respectively, during RF delivery. On deployment, there is a reduction in electrical impedance, indicating proper electrode penetration below the mucosal surface.

The hand piece was positioned under direct visualization within the anal canal, so that the needles penetrated tissue starting 1 cm distal to the dentate line (Fig. 1). The four-channel RF generator delivered RF energy (465 kHz, 2–5 Watts) to each needle electrode. Power output to each electrode was automatically modulated to achieve the selected target temperature of 85°C. RF delivery duration was 60 to 70 seconds per set. Mucosal temperature was cooled by delivering water (33 ml/min) to the base of each needle. The therapeutic goal was to create thermal lesions in the muscle below the mucosa, while preserving mucosal integrity *via* surface irrigation. Additional lesion sets were created in the region from 1 cm below to 1.5 cm above the dentate line in all four quadrants. A total of 23 to 32 lesion sets were created, with each lesion set comprised of 4 individual lesions. Dosimetry was determined by previous animal model investigation and individual patient anatomy.

The physician graded patient discomfort during insertion of the device and during RF energy delivery (none, mild, moderate, severe). After treatment, patients were given a visual analog scale ranging from “no discomfort” to “extreme pain” and asked to indicate their symptom level during treatment and two hours after treatment (0–10). Patients were permitted to go home approximately two hours after treatment.

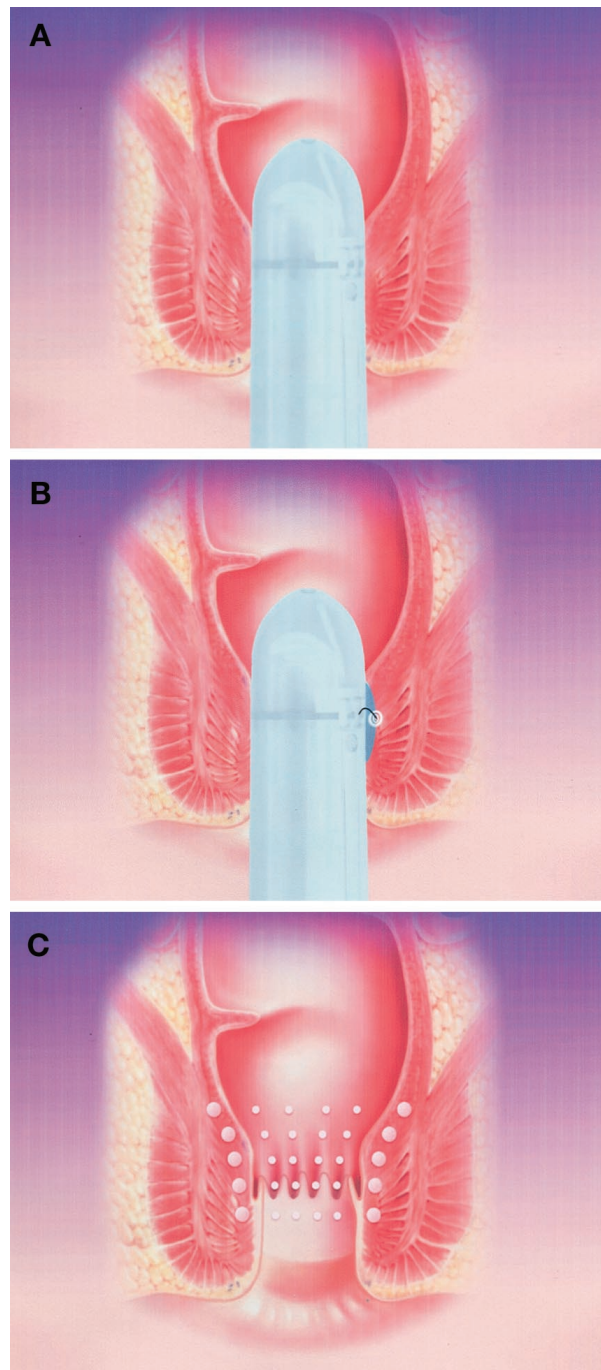


Figure 1. A. Radio-frequency energy device positioned within anal canal. B. Electrodes deployed through the mucosa into the muscle, delivery of temperature-controlled radio-frequency energy deep to the mucosa *via* electrodes, and irrigation of mucosa to cool and maintain mucosal integrity. C. Multiple deep thermal lesions beneath intact anal canal mucosa.

Follow-up

Subjects underwent anoscopy, ARM, ERUS, and PNTML six months after treatment. Subjects com-

pleted the Wexner, FIQL, and SF-36 questionnaires at 1, 2, 3, 6, and 12 months. Patients were asked whether they use protective undergarments at each interval.

Statistical Analysis

Data were analyzed using SAS software (SAS Institute, Cary, NC). Continuous outcomes from the Wexner survey, FIQL, SF-36, ARM, and PNTML were evaluated by computing the difference between the baseline and follow-up values and applying the Wilcoxon signed-rank test. The 95 percent confidence intervals were calculated and the one-sample paired *t*-test applied to the mean change from baseline to follow-up. Intention to treat analysis was not performed, because all subjects were available for follow-up at 12 months. Repeated measures analysis was performed using Generalized Estimating Equations to assess the consistency of the results over time.

RESULTS

Ten females (mean age, 55.9 ± 9.2 ; range, 44–74 years; mean body mass 67.6 ± 14 ; range, 49–89 kg) were enrolled. The mean number of years with FI symptoms was 6.7 ± 6 (Table 1). Five patients (50 percent) recalled an event associated with the onset of FI symptoms (hemorrhoidectomy (3), vaginal delivery (1), perirectal abscess drainage (1)). The most likely primary cause of incontinence was as follows: previous surgical injury ($n = 4$, internal anal sphincter or external anal sphincter defects present in 3), vaginal delivery with unilateral pudendal neuropathy ($n = 1$), sphincter defects of unknown cause ($n = 3$), unilateral pudendal neuropathy of unknown cause ($n = 1$), and low resting internal anal sphincter pressure of unknown cause.

Pertinent past medical history included vaginal delivery ($n = 8$), forceps delivery ($n = 2$), episiotomy ($n = 6$), and hysterectomy ($n = 3$). Comorbidities included diabetes mellitus in one patient. Internal hemorrhoids were present in three patients.

Feasibility

Delivery of RF energy was completed in all patients. Patients received midazolam (mean, 2.5 ± 0.6 ; range, 1.8–3 mg) and fentanyl (mean, 198 ± 70 ; range, 75–300 μg). Multiple RF sets were created (mean, 26.8 ± 2.7 ; range, 23–32), with total procedure

Table 1.
Study Population Baseline Characteristics

Characteristic	n (%)
Age (yr)	
40–49	2 (20)
50–59	6 (60)
60–69	1 (10)
70+	1 (10)
Total	10 (100)
Mean (SD) range	55.9 (9.2) 44–74
Gender	
Male	0 (0)
Female	10 (100)
Total	10 (100)
Weight (kg)	
40–49	1 (10)
50–59	3 (30)
60–69	1 (10)
70–79	3 (30)
80+	2 (20)
Mean (SD) range	67.6 (14) 49–89
Years with fecal incontinence	
0–2	3 (30)
3–5	4 (40)
6–8	0 (0)
9–11	1 (10)
12+	2 (20)
Mean (SD) range	6.7 (6) 1–20

SD = standard deviation.

time of 65.4 ± 7.8 minutes and RF energy delivery lasting 27.7 ± 4 minutes.

Safety and Tolerability

Physician-graded discomfort associated with hand piece insertion was none (80 percent), mild (10 percent), or moderate (10 percent). Physician-graded patient discomfort associated with RF energy delivery was none (50 percent), mild (10 percent), moderate (30 percent), or severe (10 percent). In those with moderate or severe discomfort, additional local anesthesia was administered and the procedure completed without discomfort. Anoscopy immediately after treatment revealed minimal mucosal injury. Median pain visual analog scale score was 3.8 (0–10) during and 0.9 (0–10) two hours after the procedure. Delayed bleeding occurred in four patients (14–21 days after treatment). This was minor in three patients with spontaneous resolution ($n = 3$), whereas one patient required anoscopy and suture ligation to control bleeding. No patient required transfusion.

Efficacy

All patients were available for 12-month follow-up, and each completed the questionnaire evaluation and objective testing as per the protocol. The median Wexner score improved from 13.5 at baseline to 5.0 at 12 months ($P = 0.006$; Fig. 2A; Table 2). This represents improvement for nine patients and slight worsening for one. With a clinical response defined as >50 percent reduction in the Wexner score, the patient response rate was 80 percent. The sum of Questions 1 and 2 of the Wexner survey was evaluated separately to assess the specific effect of this procedure on the involuntary passage of solid and liquid stool. There was a reduction in the median score from 4.0 at baseline to 1.0 at 12 months ($P = 0.02$; Fig. 2B; Table 2). The median FIQL score was improved in all 4 categories at 12 months (lifestyle (from 2.3 to 3.4), coping (from 1.4 to 2.7), depression (from 2.2 to 3.5), and embarrassment (from 1.3 to 2.8; all $P < 0.01$; Table 2).

Repeated measures analysis for the Wexner score, FIQL-lifestyle, and FIQL-depression showed that scores were slightly improved at the one-month follow-up visit ($P =$ not significant (NS)) and then significantly improved at the 2, 3, 6, and 12-month follow-up visits ($P < 0.001$). Repeated measures analysis for the FIQL-coping and FIQL-embarrassment scores showed significant im-

provements immediately, which continued at all follow-up visits ($P < 0.001$).

The median physical SF-36 score (PCS) improved from 41 to 55 ($P =$ NS), whereas the median mental SF-36 score (MCS) improved from 36 to 52 ($P =$ NS). Of note, the social functioning component of the SF-36 demonstrated improvement from 44 to 75 ($P = 0.05$; Table 2). Repeated measures analysis showed that MCS scores improved significantly for all follow-up visits ($P = 0.007$), with a slight decline at 12 months compared with the other follow-up visits. Repeated measures analysis showed that PCS scores were slightly worse at the one-month follow-up visit ($P = 0.20$) and slightly improved at the remaining visits ($P = 0.02$), with a peak at three months ($P = 0.0004$).

Protective pads were used by 7 patients at baseline, and by 2 patients at 12-month follow-up. There were no mucosal abnormalities, stricture, or ulceration noted at anoscopy at six months. There was no change in ARM resting pressure or voluntary squeeze pressure at six months. The rectoanal inhibitory reflex was present in all subjects at baseline and at follow-up. The median initial rectal sensation volume was significantly reduced from 20 ml at baseline to 15 ml at follow-up ($P = 0.046$; Table 3), whereas the median maximum tolerable rectal distention volume was significantly reduced from 245 ml at baseline to 110 ml at follow-up ($P = 0.0009$; Table 3). There was no change in PNTML at six months (Table 3).

ERUS demonstrated combined internal and external sphincter defects in 40 percent of patients, isolated internal sphincter defects in 10 percent, and isolated external defects in 10 percent. There were no significant additional findings of new defects or scar tissue at six months. There was no correlation between baseline presence of sphincter defect and clinical response.

DISCUSSION

In this prospective study of a new application of temperature-controlled RF energy for fecal incontinence, we demonstrated significant improvement in the Wexner and FIQL scores, elimination of protective pad use in most patients, and improvement in patient quality of life. An unexpected reduction in the initial rectal sensation volume and maximum tolerable rectal distention volume was noted, indicating a potential mechanism of action requiring further study. We included a group of patients with long-standing FI symptoms, confirmed by survey scores, who had failed standard nonsurgical measures for managing FI.

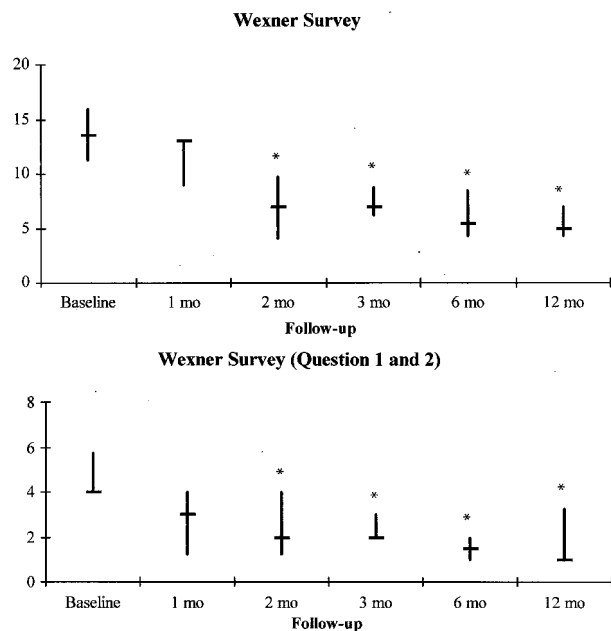


Figure 2. Median (horizontal line) and interquartile range (vertical line). A. Wexner score. B. Wexner survey, sum of solid and liquid stool incontinence Questions 1 and 2. * $P < 0.05$ compared with baseline.

Table 2.
Symptom and Quality of Life Scores

	Baseline		12 Months			12 Months-Baseline		
	N	Median (IQ Range)	N	Median (IQ Range)	P Value*	N	Mean Change (95% CI)	P Value†
Wexner score	10	13.5 (11–16)	10	5 (4–7)	0.006	10	-7.1 (-10.0, -4.2)	0.0009
Wexner Solid/Liquid Incontinence	10	4 (4.0–5.8)	10	1 (1.0–4)	0.02	10	-2.5 (-4.4, -0.6)	0.03
FIQL-Lifestyle	10	2.3 (1.9–2.8)	10	3.4 (2.6–3.7)	0.006	10	0.88 (0.45, 1.3)	0.003
FIQL-Coping	10	1.4 (1.1–2.4)	10	2.7 (1.9–3.4)	0.008	10	0.78 (0.41, 1.15)	0.002
FIQL-Depression	10	2.2 (2.1–2.6)	10	3.5 (2.9–3.7)	0.006	10	0.86 (0.42, 1.29)	0.004
FIQL-Embarrassment	10	1.3 (1.3–2)	10	2.8 (1.8–3)	0.008	10	0.97 (0.50, 1.44)	0.003
SF-36 MCS	10	36 (32–38)	10	52 (44–56)	NS	10	7.8 (-1.8, 12.5)	NS
SF-36 PCS	10	41 (38–52)	10	55 (35–55)	NS	10	5.4 (-1.4, 17)	NS
Social Function	10	44 (38–62)	10	75 (50–100)	0.05	10	22.5 (5.1, 39.9)	0.03

* SF-36 = Short Form 36; MCS = mental composite score; PCS = physical composite score; IQ = interquartile; CI = confidence interval; NS = not significant.

* = Wilcoxon signed-rank test, NS.

† = One-sample paired *t*-test, NS.

Table 3.
Anal Physiology and Ultrasound

	Baseline		6 Months			6 Months-Baseline		
	N	Median (IQ Range)	N	Median (IQ Range)	P Value*	N	Mean Change (95% CI)	P Value†
Manometric resting length	10	3.2 (3.0–3.5)	10	3 (3.0–3.3)	NS	10	-0.08 (-0.47, 0.31)	NS
Manometric resting pressure	10	39 (25–50)	10	39 (30–57)	NS	10	1.46 (-9.3, 12.2)	NS
Max squeeze pressure	10	66 (60–100)	10	63 (50–75)	NS	10	-13.2 (-36.9, 10.4)	NS
Threshold RSV	10	20 (20–50)	10	15 (10–20)	NS	10	-10 (-18.5, -1.5)	0.05
Max tolerable RSV	10	245 (200–250)	10	110 (60–120)	0.004	10	-152 (-214, -91)	0.0009
PNTML left	9	2.5 (2.2–2.8)	10	2.2 (2.1–2.3)	NS	9	-0.34 (-0.69, 0.01)	NS
PNTML right	8	2.6 (2.3–3.4)	10	2.2 (2.1–2.5)	NS	8	-1.97 (-5.01, 1.06)	NS

RSV = rectal sensation volume; PNTML = pudendal nerve terminal motor latency; NS = not significant.

* Wilcoxon signed-rank test, NS.

† One-sample paired *t*-test, NS.

The current options available to patients with FI are limited to lifestyle management, medical therapy, biofeedback, and surgery. Conservative measures have limited success because of compliance, and surgery may be offered to a select population of those who fail such measures. The most commonly used surgical technique for FI is overlapping sphincter repair, often with adjunctive levator muscle plication.⁵ This procedure is most effective in selected patients with anterior sphincter defects. Although typically safe and well-tolerated, sphincter repair requires specialized surgical skills, general or spinal anesthesia, hospitalization (ranging from 1 to 14 days),¹⁷ and significant time for recovery. Perioperative complications are reported in up to 24 percent of cases,³ and include prolonged

wound healing, infection, bleeding, fecal impaction, perineal sinus tract formation, and difficulty voiding.^{18,19} Published response rates for overlapping sphincter repair range from 69 to 93 percent.⁵ Pudendal neuropathy has been shown to be predictive of a less effective result from sphincter repair.⁵

Other techniques are currently being evaluated that include implantation of either a sacral nerve stimulator or an artificial sphincter. Early experience with these devices is promising, yet complications associated with the implanted devices have occurred frequently and include infection, extrusion, and pain.^{20,21} The safety and tolerability of RF delivery to the anal canal in this study was notable for one bleeding episode that required intervention. This may have been related to mu-

cosal injury with resultant eschar slough caused by insufficient cooling during treatment. Mucosa was intact in all patients, however, and normal in appearance at the six-month anoscopy. Some patients experienced temporary worsening of FI symptoms in the first few weeks immediately after treatment, attributed to edema, serous drainage, and mucosal healing, after which time progressive improvement in FI symptoms occurred. No other adverse events were observed, no significant pain was incurred, and the recovery process was uneventful. Because this procedure was performed on an outpatient basis under local anesthesia, hospitalization and general anesthesia were avoided. Additionally, because the procedure does not involve the implantation of a foreign body, there were no infection or extrusion complications.

The efficacy of this procedure was assessed using widely used survey instruments for FI (Wexner and FIQL), protective pad use, and general quality of life (SF-36). The Wexner and FIQL scores were significantly improved, often beginning after the one-month follow-up. Improvement continued out to 12 months, in parallel with the timing of normal wound healing.¹¹ Significant improvement was also seen in Questions 1 and 2 of the Wexner Score, indicating that some patients still experience gas incontinence, yet much of the solid and liquid stool incontinence is improved. This improvement in the Wexner score is comparable to published results of the efficacy of overlapping sphincter repair.¹⁹

The improvement in SF-36 scores, although not statistically significant, was nonetheless present. The social function parameter of the SF-36, typically affected by FI symptoms, was significantly improved at 6 and 12 months after this procedure. The SF-36 is an instrument for general, nonspecific QOL, and therefore may be affected by comorbid states. There were no significant changes in ERUS at six months, consistent with the microscopic nature of these lesions and previous ERUS findings from an animal protocol.

There are three possible mechanisms that may explain the observed therapeutic effect of RF energy delivery for FI. First, heating of tissue to approximately 65°C results in an immediate linear contraction of collagen protein to 25 to 33 percent of its initial length, with subsequent tissue shrinkage.²² Furthermore, as normal wound healing processes commence, thermal lesions are replaced by fibroblasts and collagen and are then remodeled over a period of up to 12 months.¹¹ The net effect is shrinkage of the treated tissue, as observed in the treatment of snoring

and obstructive sleep apnea,^{12,23} benign prostatic hyperplasia,²⁴ and joint capsule laxity.²⁵ This thermal effect reduces tissue compliance, as described in the use of RF for the treatment of gastroesophageal reflux disease.²⁶ A compliance change can have an effect on the barrier function of the sphincter, without a concomitant increase in basal pressure.²⁷

A second possible mechanism is that RF treatment of the upper portion of the anal canal, including the transition zone, is related to the observed reduction in the ARM rectal distention volumes. Subjects were able to sense the initial distention at lower volumes and were able to tolerate much lower maximum volumes of rectal distention. This may result in earlier sensing of an impending FI event, and provide additional time to reach the lavatory.

A third possible mechanism may be related to alteration of the sampling reflex. If a sampling reflex exists, as described by Miller *et al.*,²⁸ and if this reflex contributes to FI in some patients, then RF may alter the sampling pattern and reduce FI symptoms, although the rectoanal inhibitory reflex remained intact in all patients.

The promising results of this trial should be considered in light of its potential limitations, including the nonrandomized study design, the small number of subjects, and the subjective nature of the questionnaire scoring. Although a placebo effect is possible, the persistence of symptom score improvement with repeated measures analysis over a period of 12 months makes a significant placebo effect unlikely.

We speculate that the ideal future candidate for this procedure may have at least weekly incontinence and is dissatisfied with medical therapy, but is not willing to undergo or is not eligible for surgical intervention. Previous overlapping sphincter repair will not likely be an exclusion criterion, nor will pudendal neuropathy. Patients with a single anterior sphincter defect will likely to be offered surgery as first line treatment. Further, patients with diarrhea or constipation as a sole cause of FI are unlikely candidates for RF treatment. We recognize that further study regarding durability, subgroup analysis, mechanism of action, and dosimetry may result in our needing to refine our present opinion.

CONCLUSION

Radio-frequency energy delivery deep to the mucosa of the anal canal for treatment of FI is a new modality that, in this study group, safely improved the Wexner and FIQL scores, eliminated protective pad use in most patients, and improved patient quality of

life. These symptom improvements were accompanied by a reduction in the threshold and maximal rectal distention volumes on ARM, alluding to a possible, yet undefined mechanism. A U.S. multicenter trial is underway to define further the precise role and mechanism of action of RF delivery for the long-term management of this disorder.

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